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UNCLAS SECTION 01 OF 02 ANKARA 007016

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SENSITIVE

E.O. 12958: N/A

TAGS: [ETRD](#) [KIPR](#) [TU](#)

SUBJECT: Ambassador Discusses IPR Protection with Health Minister

REF: (A) STATE 263410 (B) ANKARA 6966

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¶11. (SBU) Summary: In his meeting with the Health Minister, the Ambassador raised the USG's concerns regarding lack of data protection and patent linkage in Turkey, and urged the GOT to take immediate action to resolve these problems. The Ambassador pointed out the specific problem Eli Lilly was facing with its patented product Zyprexa, and asked the GOT not to issue marketing approval for generic copies of patented U.S. products. The Health Minister noted the GOT's recent decision to start implementing data exclusivity in 2005, which he claimed would resolve that issue. The Minister mentioned the court ruling on the Zyprexa case, which allowed the Ministry to move forward with the licensing process. The Minister stated that the court ruling was binding and the Ministry would proceed accordingly unless a new ruling supported Eli Lilly's appeal. The Ambassador advised the Minister to take the initiative to bring the research-based and generic producers together for a long-term solution to this problem. He also pointed out possible consequences, such as loss of GSP privileges, if Turkey failed to uphold its TRIPS obligations. End Summary.

¶12. (SBU) In his December 15 meeting with Health Minister Recep Akdag, the Ambassador raised intellectual property problems research-based pharmaceuticals manufacturers face in Turkey, particularly lack of data protection and patent linkage. The Ambassador pointed out that these issues, also brought up by Senator Lugar and Under Secretary Larson in their correspondence with the

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Minister, were important both for improving U.S.-Turkey bilateral relations and to make good use of the creative potential of Turkish people. The Ambassador said Eli Lilly's recent decision to downsize in Turkey was a matter of concern. The Ambassador pointed out the other consequences the GOT may face if it failed to realize its obligations under WTO TRIPS, such as loss of privileges under the Generalized System of Preferences (GSP). The Ambassador made special reference to an IP problem Eli Lilly was facing in Turkey with its patented product Zyprexa. The Ambassador stated that due to a lack of coordination between the Health Ministry and the Patent Institute, a generic copy of Zyprexa was at the stage of receiving approval from the Health Ministry, and the Zyprexa patent would be infringed. The Ambassador left a paper explaining patent linkage with the Minister.

¶13. (SBU) Minister Akdag said the GOT had recently decided to move the implementation date for data exclusivity from late 2007 to early 2005. Akdag stated that the EU too, closely followed this issue and expected Turkey to realize its obligations regarding data exclusivity. Akdag noted that the implementation would not cover licenses issued and applications made before 2005. Regarding Zyprexa, Akdag said this issue was in litigation and the Ministry was not authorized to intervene in the judicial process. Akdag said the court made a ruling on this case, which Eli Lilly may appeal. The court ruled out Eli Lilly's demand to stop the Ministry's licensing process, based on the Patent Law, which states that patent infringement does not take place until a new license for a generic product is issued. Akdag added that the Court received an expert opinion on this case, which pointed out that the two products (the original and generic) were using different versions of the same molecule, but only the molecule Zyprexa was patented in Turkey. Akdag said using slightly different version of the same molecule and marketing it as a different one is a problem the pharmaceuticals industry faced worldwide.

¶4. (SBU) The Ambassador reiterated the long-term importance of implementing a patent linkage system to avoid patent infringement and offered USG assistance in establishing such a system. He suggested that the GOT take the initiative to bring together the research-based companies and generic producers. The Ambassador pointed out that the two groups needed each other to exist, and as long as this conflict remained unresolved, Turkish doctors' and patients' access to innovative drugs would be limited. Minister Akdag asked for the Ambassador's assistance in bringing the two groups together, and noted that Turkey, like many other EU candidate countries, needed to go through a transition period to fully implement data exclusivity.

¶5. (SBU) Comment: The GOT has not "solved" the data exclusivity problem by bringing forward planned implementation to January 2005, since this allows approval of copies of drugs which should, under both TRIPS and the EU customs union, have long since been entitled to data exclusivity protection, with huge losses to research-based industry. Embassy understands that this issue is still in negotiation with the European Commission in the context of the Trade Barrier Report. Edelman